

REMARKS

Entry of the foregoing and reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

Claims 12-19 are amended herein. New claims 24-31 are added. Basis for the amendments to the claims and new claims may be found throughout the specification and claims as-filed, especially at page 3, lines 7-12, page 6, lines 16-17, page 7, lines 16-17 and 24; and Example 1.

As amended the claims are directed to methods of increasing the level of differentiation of skin fibroblasts comprising applying to the skin, an effective amount of ascorbic acid or one of its analogues to the subject for a period of time effective to increase the level of differentiation of skin fibroblasts. The new claims are directed to a specific period of time (page 7, line 24); specific effects of the increased cell differentiation (page 3, lines 7-12 and page 6, lines 16-17); and specific percentage amounts of ascorbic acid (page 7, lines 16-17 and Example 1).

Claim Rejections Under 35 U.S.C. §§ 112, second paragraph

Claims 13, 17, 16-19, and 21 stand rejected under 35 U.S.C. § 112, second paragraph, as purportedly indefinite.

Claim 13 stands rejected, as the phrase "its analogues" purportedly lacks antecedent basis. Claims 12 and 13 are amended herein to recite "analogues thereof" to provide antecedent basis.

Claims 16-19 stand rejected for the recitation of "vigars". The claims are amended herein to replace "vigars" with "sugars".

In light of the above remarks, Applicants request that the rejections under 35 U.S.C. § 112, second paragraph be withdrawn.

Claim Rejections Under 35 U.S.C. §§ 102 and 103

Claims 12, 14 and 15 stand rejected under 35 U.S.C. § 102(b) as purportedly anticipated by Lerner (U.S. Patent No. 5,470,874). Lerner purportedly discloses a topical composition containing at least 10 to 25% ascorbic acid and at least 0.5% to 5% proanthocyanidine (as radical scavengers) for collagen synthesis and wound healing. Although noting that Lerner fails to disclose any effect on differentiation of fibroblasts or keratinocytes, the Examiner states that this property is inherent to Lerner.

"[A]nticipation requires the presence in a single prior art disclosure of all elements of a claimed invention as arranged in the claims." *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 U.S.P.Q. 253, 256 (Fed. Cir. 1985). Lerner fails to describe or even suggest all of the elements of the rejected claims. To this end, Applicants submit that the effects on differentiation by the claimed methods are not inherent. Specifically, the fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993).

The Office Action states that Lerner meets the elements of the present claims because Applicants have "merely found the mechanism of collagen synthesis" and that it is known that the stimulation of fibroblasts stimulates collagen synthesis. Applicants submit that the effects of the present invention are in fact not related to

collagen synthesis. Instead, the differentiation effects are related to cell renewal and barrier function (see specification, page 3, lines 7-14). Rather, skin is renewed at a more rapid rate, and skin is more radiant and less dull (see page 6, lines 16-17 of specification). Thus, the effect of differentiation is not inherent to the methods disclosed by Lerner. Lerner discloses a topical composition for collagen synthesis and wound healing, and the effects of the present invention as recited in the claims are not related to collagen synthesis.

Applicants also submit herewith new claims 24-29. New independent claims 26 and 27 recite the subject matter of claims 12-13 and also recite that the effective amount of ascorbic acid or analogues thereof is about 3% to about 10% of the total weight of the composition. In contrast, Lerner discloses a composition containing 10-25% of ascorbic acid. Thus, claims 12, 14, and 15, as well as new claims 26-29, are not anticipated by Lerner.

Claims 13, 17 and 21 stand rejected under 35 U.S.C. § 102(b) as purportedly anticipated by Perricone (U.S. Patent No. 5,574,063). Perricone discloses a method for the therapeutic treatment of skin disorders caused by collagen deficiency by topically applying a fatty ester of ascorbic acid to the affected skin areas.

As with Lerner, the Office Action notes that Perricone is silent with regard to differentiation (in this case, differentiation of keratinocytes) but that it is known that the stimulation of fibroblasts produces keratinocytes growth factors and in turn stimulates collagen synthesis. Applicants submit that the effects of the present invention are in fact not related to collagen synthesis. Instead, the differentiation effects are related to cell renewal and barrier function and skin is renewed at a more

rapid rate, and skin is more radiant and less dull. Thus, the effects of differentiation are not inherent to the methods disclosed by Perricone. Perricone discloses a method for the therapeutic treatment of skin disorders caused by collagen deficiency, and the effects of the present invention as recited in the claims are not related to collagen synthesis.

Applicants also submit herewith new claims 24-29. New independent claims 26 and 27 recite the subject matter of claims 12-13 and also recite that the effective amount of ascorbic acid or analogues thereof is about 3% to about 10% of the total weight of the composition, which is not recited by Perricone.

Thus, claims 13, 17 and 21, as well as the new claims, are not anticipated by Perricone.

Claims 13 and 16-23 are rejected under 35 U.S.C. § 103(a) as purportedly unpatentable over Lerner as applied above and further in view of Perricone. As set forth in M.P.E.P § 2142, in order to establish a prima facie case of obviousness, three criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, (2) there must be a reasonable expectation of success, and (3) the prior art references must teach or suggest all the claim limitations. Applicants submit that these criteria are not met by the cited references, alone or in combination. The Office Action states that it would have been obvious to the skilled artisan to modify the compositions of Lerner by substituting vitamin C with fatty acid esters of ascorbic acid as motivated by Perricone. Applicants traverse.

As noted above, Lerner as well as Perricone are concerned with collagen synthesis and collagen deficiency. This disclose regarding collagen synthesis is distinct from the present invention, which as claimed is directed to the increase of the level of differentiation of fibroblasts/keratinocytes for better renewal of cells and better barrier function. There is no mention of such effects in Lerner or Perricone. Therefore, there is no motivation for the skilled artisan to combine Lerner with Perricone.

In addition, Lerner with Perricone fail to recite all of the elements of the present invention, as neither reference (or both references combined) recite the elements of the claimed invention, as neither reference discloses the differentiation of cells, such as keratinocytes as in claim 13.

In light of the above remarks and amendments to the claims, Applicants request that the rejections under 35 U.S.C. §§ 102 and 103 be withdrawn.

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CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

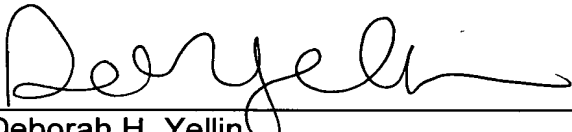
In the event that there are any questions concerning this amendment or the application in general, the Examiner is respectfully requested to telephone the undersigned so that prosecution of the application may be expedited.

Respectfully submitted,

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